

## REMARKS

This Amendment is submitted in reply to the final Office Action mailed on April 25, 2008. No fee is due in connection with this Amendment. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 115808-509 on the account statement.

Claims 35, 37-52 and 54-68 are pending in this application. Claims 1-34, 36 and 53 were previously canceled without prejudice or disclaimer. In the Office Action, Claim 35 is rejected under 35 U.S.C. §112. Claims 35, 37-52 and 54-68 are rejected under 35 U.S.C. §103. In response, Claims 35, 52, 61 and 67 have been amended. The amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claim 35 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Patent Office asserts that the term “sufficient” is indefinite because it is a relative term without a defined range. See, Office Action, page 3, lines 1-2. The Patent Office further asserts that the term “affects” is indefinite because it is unclear whether the effect is positive or negative. See, Office Action, page 3, lines 2-4. In response, Applicants have amended Claim 35 to recite, in part, a method of improving or maintaining absorption of vitamin E in a pet animal comprising the step of feeding the pet an effective amount of an edible composition to improve or maintain or promote the pet's lipid absorption capacity. The amendments do not add new matter. The amendments are supported in the Specification, for example, at paragraph 33, lines 1-8; and paragraph 102, lines 2-6. Applicants have replaced the allegedly indefinite term “sufficient” with “effective.” Furthermore, Applicants have replaced the allegedly indefinite term “affects” with the phrase “to improve or maintain or promote” to clarify that the composition has the positive effect of improving or maintaining or promoting the pet's lipid absorption capacity. As such, Applicants respectfully submit that currently amended Claim 35 is not indefinite.

Accordingly, Applicants respectfully request that the rejection of Claim 35 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 35, 37-52 and 54-68 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,471,999 B2 to Couzy et al. (“Couzy”) in view of U.S.

Patent No. 5,290,571 to Bounous et al. ("*Bounous I*") or U.S. Patent No. 5,451,412 to Bounous et al. ("*Bounous II*"), and further in view of "Micronutrient status in patients with gastrointestinal disease" to Simpson et al. ("*Simpson*"), "Effect of Bacterial or Porcine Lipase With Low- or High-Fat Diets on Nutrient Absorption in Pancreatic-Insufficient Dogs" to Suzuki et al. ("*Suzuki*") and WO 01/62280 A2 to Margolin et al. ("*Margolin*"). In response, Applicants have amended Claims 35, 52, 61 and 67. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

Currently amended independent Claims 35 and 52 recite, in part, a method of maintaining or improving the level of vitamin E in a pet animal comprising feeding the pet animal an effective amount of an edible composition to improve or maintain the pet's lipid absorption capacity, the edible composition comprising a pancreatic function-promoter, a liver function-promoter, and an intestinal mucosa function-promoter, wherein the liver function-promoter comprises between about 0.1% and about 1% by weight of the edible composition on a dry matter basis and the intestinal mucosa function-promoter comprises between about 0.1% and about 20% by weight of the edible composition on a dry matter basis.

Similarly, currently amended independent Claim 61 recites, in part, a composition comprising a pancreatic function promoter, a liver function promoter, and an intestinal mucosa function promoter in amounts effective to promote or maintain or improve the lipid absorption capacity of a pet, wherein the liver function promoter comprises between about 0.1% and about 1% by weight of the composition on a dry matter basis and the intestinal mucosa function promoter comprises between about 0.1% and about 20% by weight of the composition on a dry matter basis.

Currently amended independent Claim 67 recites, in part, a method of improving the appearance of a pet comprising the step of increasing a pet's serum vitamin E level by feeding the pet a diet that maintains or improves the pet's lipid absorption capacity and comprises a fat emulsifier or fat emulsification system, a fat transportation agent, and an acidifying agent. These amendments do not add new matter.

These amendments are supported in the Specification at, for example, paragraph 20, lines 1-4; paragraph 22, lines 1-3; paragraph 23, lines 1-3; paragraph 25, lines 1-2; paragraph 30, lines

5-8; paragraphs 40-44; paragraph 60, lines 5-12; paragraph 67, lines 5-10; paragraph 70, lines 1-4 and 6-11; paragraphs 141-143; and paragraphs 147-149..

Several studies have shown that older pets, especially cats, have a decreased capacity to digest lipids. See, Specification, paragraph 3, lines 1-5. Because valuable nutrients such as vitamin E are absorbed only with long-chain fatty acids, a decrease in the ability to digest lipids can lead to vitamin deficiencies and adverse health effects on a pet. See, Specification, paragraph 2, lines 1-5. Therefore, the present claims provide a composition for a pet that contains a pancreatic function-promoter, a liver function-promoter, and an intestinal mucosa function-promoter in amounts effective to increase the capacity of the pet to digest lipids. See, Specification, paragraphs 19-20; paragraph 30, lines 5-8; paragraph 33, lines 1-7. 8, lines 1-8. The pancreatic function-promoter may be an acidifier which reduces the gut pH of the pet by approximately one point on the fourteen point pH scale. See, Specification, paragraph 54, lines 1-4. The liver function-promoter is present in an amount between about 0.1% and about 1% by weight of the composition on a dry mass basis in order to enhance the capacity of the pet to digest lipids. See, Specification, paragraph 60, lines 5-15; paragraph 63, lines 4-8. The intestinal mucosa function-promoter is present in an amount between about 0.1% and about 20% by weight of the composition on a dry matter basis to further increase or promote the capacity of the pet to digest lipids. See, Specification, paragraph 67, lines 5-10; paragraph 68, lines 8-11; paragraph 70, lines 1-4. In contrast, the cited references are deficient with respect to the present claims.

Even if combinable, the cited references fail to disclose or suggest a composition comprising a pancreatic function-promoter, a liver function-promoter, and an intestinal mucosa function-promoter, wherein the liver function-promoter comprises between about 0.1% and about 1% by weight of the edible composition on a dry matter basis and the intestinal mucosa function-promoter comprises between about 0.1% and about 20% by weight of the edible composition on a dry matter basis as required, in part, by independent Claims 35, 52 and 61. The Patent Office relies on *Couzy* for the disclosure of a composition comprising a liver function-promoter such as taurine and an intestinal mucosa function-promoter such as a probiotic microorganism. See, Office Action, page 4, lines 1-8. However, nowhere does *Couzy* disclose or suggest an amount of the liver function-promoter or intestinal mucosa function-promoter. *Couzy* merely discloses that its milk powder may be supplemented with further protein and

amino acid sources such as whey protein or taurine. See, *Couzy*, column 3, lines 25-32. Thus, *Couzy* fails to disclose or suggest any effective amounts of the liver function-promoter or intestinal mucosa function-promoter.

*Bounous I* and *Bounous II* are entirely directed to whey protein concentrates for general immunoenhancement. See, *Bounous I*, column 1, lines 21-29; *Bounous II*, column 1, lines 15-23. Although the Patent Office relies on *Bounous I* and *Bounous II* for the disclosure of glutathione, the references merely disclose increasing the concentration levels of glutathione in animal organs by administering a whey protein concentrate. See, *Bounous I*, column 11, lines 46-51; *Bounous II*, column 10, lines 38-42, column 11, lines 38-43. Nowhere do *Bounous I* or *Bounous II* disclose an amount of a liver function-promoter such as glutathione or an intestinal mucosa function-promoter. *Simpson*, *Suzuki* and *Margolin* are directed to problems associated with fat malabsorption and fail to disclose dietary compositions. See, Specification, paragraph 8, lines 1-4. As such, the cited references fail to disclose or suggest a composition wherein the liver function-promoter comprises between about 0.1% and about 1% by weight of the edible composition on a dry matter basis and the intestinal mucosa function-promoter comprises between about 0.1% and about 20% by weight of the edible composition on a dry matter basis as required, in part, by independent Claims 35, 52 and 61 and Claims 37-51, 54-60 and 62-66 that depend therefrom.

Moreover, the cited references fail to disclose or suggest a composition comprising an acidifying agent as required, in part, by independent Claim 67. The Patent Office relies on *Couzy* for the disclosure of pancreatic function-promoters such as inulin or chicory fibers. See, Office Action, page 4, lines 6-7. However, inulin and chicory fibers are not acidifiers but rather prebiotics. See, Specification, paragraph 58, lines 3-6. The Patent Office seems to suggest that *Couzy* discloses a pancreatic function-promoter such as lactic acid. See, Office Action, page 4, lines 3-6. However, the portions of *Couzy* cited by the Patent Office merely disclose probiotics that produce lactic acid, not the inclusion of lactic acid as a probiotic component in the composition. See, *Couzy*, column 40-42. As discussed previously, *Bounous I* and *Bounous II* are entirely directed to whey protein concentrates and, as such, fail to disclose an acidifying agent. Furthermore, the remaining cited references are directed to the effects of fat malabsorption and fail to disclose dietary compositions. See, Specification, paragraph 8, lines 1-4. Therefore, the cited references fail to disclose or suggest a composition comprising an

acidifying agent as required, in part, by independent Claim 67 and Claim 68 that depends therefrom.

Furthermore, the cited references fail to disclose or suggest feeding a pet animal a diet or an effective amount of a composition comprising a pancreatic function-promoter, a liver function-promoter, and an intestinal mucosa function-promoter to maintain or improve the pet's lipid absorption capacity as required, in part, by currently amended independent Claims 35, 52 and 67. *Couzy* is entirely directed to reducing the gastrointestinal problems associated with the consumption of lactose. See, *Couzy*, column 2, lines 1-4. *Couzy* teaches that adding lactase to a milk powder composition improves the general gastrointestinal tolerance of the pet. See, *Couzy*, column 2, lines 1-9. Nowhere does *Couzy* disclose or suggest a diet or an effective amount of a composition for improving or maintaining a pet's lipid absorption capacity. Similarly, *Bounous I* and *Bounous II* are entirely directed to whey protein concentrates for general immunoenhancement. See, *Bounous I*, column 1, lines 21-29; *Bounous II*, column 1, lines 15-23. Nowhere do *Bounous I* or *Bounous II* disclose or suggest a diet or an effective amount of a composition for improving or maintaining a pet's lipid absorption capacity. In fact, the Patent Office admits that *Couzy*, *Bounous I* and *Bounous II* fail to disclose or suggest enhancing lipid digestibility. See, Office Action, page 5, line 12.

Nevertheless, the Patent Office asserts that one of ordinary skill in the art would have been motivated to combine the teachings of *Simpson*, *Suzuki*, and *Margolin* with the compositions of *Couzy*, *Bounous I* and *Bounous II* to arrive at the present claims. See, Office Action, page 5, lines 13-21; page 6, lines 1-2 and 5-17. However, *Simpson* merely teaches that defects in fat digestion can lead to a deficiency in several vitamins, including vitamin E. See, *Simpson*, paragraph 3, lines 1-3. *Suzuki* merely teaches that high-fat and high-protein diets optimize fat absorption with both enzymes. See, *Suzuki*, Conclusions. Likewise, *Margolin* merely recognizes that vitamin E deficiency is one of several consequences of fat malabsorption. See, *Margolin*, page 1, lines 10-12. *Simpson*, *Suzuki* and *Margolin* all fail to address the problem of vitamin E deficiency in a dietary framework or provide a dietary solution to the fat malabsorption. See, Specification, paragraph 8, lines 1-4. As such, the cited references fail to disclose or suggest feeding a pet animal a diet or an effective amount of a composition to maintain or improve the pet's lipid absorption capacity in accordance with independent Claims 35, 52 and 67.

The cited references also fail to disclose or suggest a composition comprising a pancreatic function promoter, a liver function promoter, and an intestinal mucosa function promoter in amounts effective to promote or maintain or improve the lipid absorption capacity of a pet as required, in part, by independent Claim 61. As discussed previously, *Couzy*, *Bounous I* and *Bounous II* fail to disclose an effective amount of a composition comprising a pancreatic function-promoter, a liver function-promoter, and an intestinal mucosa function-promoter to improve or maintain a pet's lipid absorption capacity. Furthermore, *Simpson*, *Suzuki* and *Margolin* fail to provide a dietary solution to the fat malabsorption. Therefore, even if the cited references disclose a pancreatic function-promoter, a liver function-promoter and an intestinal mucosa function-promoter, the cited references fail to disclose or suggest such claimed elements in amounts effective to improve or maintain the ability of a pet to digest lipids as required, in part, by independent Claim 61.

Accordingly, Applicants respectfully request that the rejection of Claims 35, 37-52 and 54-68 under 35 U.S.C. §103(a) to *Couzy* in view of *Bounous I* or *Bounous II* and further in view of *Simpson*, *Suzuki* and *Margolin* be withdrawn.

In the Office Action, Claims 35, 37-52 and 54-68 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 02/15719 to Fuchs et al. ("*Fuchs*") in view of U.S. Patent No. 5,290,571 to Bounous et al. ("*Bounous I*") or U.S. Patent No. 5,451,412 to Bounous et al. ("*Bounous II*"), and further in view of "Micronutrient status in patients with gastrointestinal disease" to Simpson et al. ("*Simpson*"), "Effect of Bacterial or Poreine Lipase With Low- or High-Fat Diets on Nutrient Absorption in Pancreatic-Insufficient Dogs" to Suzuki et al. ("*Suzuki*") and WO 01/62280 A2 to Margolin et al. ("*Margolin*"). In response, Applicants have amended Claims 35, 52, 61 and 67. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

Even if combinable, the cited references fail to disclose or suggest a composition comprising a pancreatic function-promoter, a liver function-promoter, and an intestinal mucosa function-promoter, wherein the liver function-promoter comprises between about 0.1% and about 1% by weight of the edible composition on a dry matter basis and the intestinal mucosa function-promoter comprises between about 0.1% and about 20% by weight of the edible composition on a dry matter basis as required, in part, by independent Claims 35, 52 and 61. As

discussed previously, *Bounous I*, *Bounous II*, *Simpson*, *Suzuki* and *Margolin* fail to disclose or suggest the claimed amounts of the liver function-promoter or intestinal mucosa function-promoter. Furthermore, *Fuchs* merely discloses that the wet weight percentage of protein, which includes whey protein, in the composition is 4.8. See, *Fuchs*, page 13, Table, Example 1. Likewise, *Fuchs* fails to disclose any weight percentage of liver-function promoters such as taurine. Instead, *Fuchs* merely discloses that the wet weight percentage of “vitamins and minerals” in its composition are at least 5% of the Recommended Daily Allowance. See, *Fuchs*, page 13, Table, Example 1. Nowhere does *Fuchs* disclose or suggest the weight percentage of whey protein or taurine on a dry matter basis. Thus, the cited references fail to disclose or suggest a composition wherein the liver function-promoter comprises between about 0.1% and about 1% by weight of the edible composition on a dry matter basis and the intestinal mucosa function-promoter comprises between about 0.1% and about 20% by weight of the edible composition on a dry matter basis as required, in part, by independent Claims 35, 52 and 61.

Moreover, the cited references fail to disclose or suggest a composition comprising an acidifying agent as required, in part, by independent Claim 67. The Patent Office relies on *Fuchs* for the disclosure of pancreatic function-promoters such as probiotics and prebiotics. See, Office Action, page 7, lines 7-18. However, nowhere does *Fuchs* disclose or suggest an acidifying agent, nor does the Patent Office cite support for such claimed element. As discussed previously, the other cited references also fail to disclose or suggest an acidifying agent. Therefore, the cited references fail to disclose or suggest a composition comprising an acidifying agent as required, in part, by independent Claim 67 and Claim 68 that depends therefrom.

Furthermore, the cited references fail to disclose or suggest feeding a pet animal a diet or an effective amount of a composition comprising a pancreatic function-promoter, a liver function-promoter, and an intestinal mucosa function-promoter to maintain or improve the pet's lipid absorption capacity as required, in part, by currently amended independent Claims 35, 52 and 67. The Patent Office relies on *Fuchs* for the disclosure of the claimed elements of a pancreatic function-promoter such as a probiotic, a liver function-promoter such as taurine and an intestinal mucosa function-promoter such as whey protein. See, Office Action, page 7, lines 3-18. However, *Fuchs* is entirely directed to a nutritional composition for patients with limited appetites or reduced gastric pepsin digestion capabilities. See, *Fuchs*, page 1, lines 5-12. The whey protein is included in the composition over other proteins merely because it is rapidly

emptied from the stomach, thereby allowing a rapid return of appetite to sick patients. See, *Fuchs*, page 11, lines 27-32. Nowhere does *Fuchs* disclose or suggest a diet or an effective amount of a composition to maintain or improve the pet's lipid absorption capacity.

As discussed previously, *Bounous I* and *Bounous II* also fail to disclose or suggest a diet or an effective amount of a composition for maintaining or improving lipid absorption. In fact, the Patent Office admits that *Fuchs*, *Bounous I* and *Bounous II* fail to disclose improving lipid absorption and instead relies on *Simpson*, *Suzuki* and *Margolin* for the motivation to provide a dietary composition in accordance with the present claims to promote the capacity of a pet to absorb vitamin E. See, Office Action, page 8, lines 12-21; page 9, lines 1-17. As discussed previously, *Simpson*, *Suzuki* and *Margolin* are directed to problems associated with fat malabsorption and fail to disclose dietary compositions. See, Specification, paragraph 8, lines 1-4. Therefore, the cited references fail to disclose or suggest feeding a pet animal a diet or an effective amount of a composition to maintain or improve the pet's lipid absorption capacity in accordance with independent Claims 35, 52 and 67.

The cited references also fail to disclose or suggest a composition comprising a pancreatic function promoter, a liver function promoter, and an intestinal mucosa function promoter in amounts effective to promote or maintain or improve the lipid absorption capacity of a pet as required, in part, by independent Claim 61. As discussed previously, *Fuchs*, *Bounous I* and *Bounous II* fail to disclose an effective amount of a composition comprising a pancreatic function-promoter, a liver function-promoter, and an intestinal mucosa function-promoter to improve or maintain a pet's lipid absorption capacity. Furthermore, *Simpson*, *Suzuki* and *Margolin* fail to provide a dietary solution to the fat malabsorption. Therefore, even if the cited references disclose a pancreatic function-promoter, a liver function-promoter and an intestinal mucosa function-promoter, the cited references fail to disclose or suggest such components in amounts effective to improve or maintain the ability of a pet to digest lipids as required, in part, by independent Claim 61.

Accordingly, Applicants respectfully request that the rejection of Claims 35, 37-52 and 54-68 under 35 U.S.C. §103(a) to *Fuchs* in view of *Bounous I* or *Bounous II* and further in view of *Simpson*, *Suzuki* and *Margolin* be withdrawn.



For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Patent Office is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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BY \_\_\_\_\_

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